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Managing Sanctions and Export Control Risks in the Health Care Industry

Over the past 15 years, pharmaceutical manufacturers, medical device companies, and other participants in the health care industry have been regular targets of U.S. Foreign Corrupt Practices Act ("FCPA") enforcement actions brought by the U.S. government. FCPA cases levied against health care companies have commanded significant attention, and many companies have responded by implementing robust anti-corruption compliance programs consisting of policies and procedures, employee training, risk-based due diligence, and proactive compliance testing and monitoring.

Recent settlements suggest that a new trend may be emerging: the U.S. government bringing enforcement actions against health care companies for violating economic sanctions and export control laws. Like the FCPA, U.S. economic sanctions and export control laws have broad extraterritorial application. Many health care companies are large organizations with expansive international operations and distributors and end users dispersed throughout the world. These attributes make health care industry participants likely to confront sanctions- and export control-related regulatory challenges, and natural targets for enforcement actions.

Penalties for violations of economic sanctions and export control laws can be severe. In addition to civil fines and criminal penalties, running afoul of these laws can result in non-monetary consequences such as loss of export privileges, the imposition of compliance monitorships, U.S. Securities and Exchange Commission reporting obligations, and reputational harm. Recent settlements illustrate these consequences are not merely hypothetical.

This article discusses sanctions- and export control-related risks affecting the health care industry, as well as steps that companies may take to mitigate their exposure.

I. RISK AREAS & PROACTIVE MITIGATION STEPS

A. Indirect Exports to Restricted Countries

Many U.S.-based health care companies with international operations are aware of the restrictions and licensing requirements associated with exporting products to sanctioned countries. To deal with this risk, these companies have designed compliance programs to prevent direct sales to countries subject to comprehensive sanctions or wide-ranging export controls. It is therefore unsurprising that many enforcement actions targeting health care companies have involved *indirect* exports to entities in restricted countries.

During the last decade, a number of U.S.-based pharmaceutical and medical device companies have been subject to enforcement actions for selling products to embargoed countries through foreign affiliates or third parties. The most notable of these enforcement actions involved U.S. and foreign affiliates of Alcon, which entered into coordinated settlements with the Office of Foreign Assets Control ("OFAC") and the Bureau of Industry and Security ("BIS") in July 2016 to resolve alleged violations of sanctions and export control laws. OFAC and BIS alleged that an Alcon subsidiary in Switzerland purchased U.S.-origin products from an Alcon U.S. affiliate and subsequently reexported those items to Iran and Syria. The Alcon entities ultimately agreed to pay a fine of over $9.4 million to resolve their potential liability.

More recently, in February 2017, United Medical Instruments, Inc. ("UMI"), a U.S.-based supplier of ultrasound equipment, agreed to pay over $500,000 to OFAC in order to resolve alleged violations of the Iranian sanctions.[1] As in the Alcon case, OFAC alleged that UMI exported products to Iranian end users via intermediaries in third countries. Other companies also have entered into settlement agreements with OFAC, BIS, and the Department of Justice based on similar fact patterns.

These settlements underscore the importance of robust due diligence, ongoing monitoring, and periodic auditing of supply chain activities. For example, before exporting products, a company should identify the ultimate destination and end user of the products, as well as any intermediate parties—such as distributors and sales agents—involved in the transaction. Companies should exercise heightened diligence if a party to any transaction is located in a known gateway to sanctioned countries (*e.g.*, China, the United Arab Emirates, Turkey) or do not have well-established reputations. Companies exporting products to third-party distributors and sales agents may seek contractual protections, such as covenants, to comply with applicable sanctions and export control laws and to refrain from doing business with embargoed countries or parties targeted by list-based sanctions. Finally, companies should perform ongoing monitoring and periodic audits of their compliance with applicable sanctions and export control laws. Depending on a company's risk profile and the availability of resources, monitoring and auditing activities may be performed either in person or remotely.

B. Violations of Licenses and Exemptions

Another potential avenue of liability for health care companies is the provision of products or services that exceed export authorizations. OFAC has issued general licenses—and BIS maintains license exceptions—that authorize transactions that otherwise would be prohibited by U.S. sanctions or export control laws. These general licenses and license exceptions, which vary in scope and are updated periodically, usually contain limitations. For example, OFAC's general license that allows for the exportation and reexportation of certain medicine and medical devices to Iran does not cover exports or reexports to military, intelligence, or law enforcement purchasers (e.g., military hospitals), or to parties included on the Specially Designated Nationals List. These carve-outs to licenses can create compliance challenges, particularly for companies with limited compliance resources.

OFAC and BIS also grant specific licenses authorizing transactions that are not within the scope of existing general licenses and license exceptions. Specific licenses typically are limited by activity, end user, and duration. Companies that intentionally or inadvertently violate the terms of a specific license—for example, by engaging in activities outside the scope of the license or making sales that are within scope but occur after the license has expired—risk incurring liability.

Companies can take several steps to mitigate the risk of non-compliance with applicable licenses and license exceptions. First, companies may designate one or more employees as the primary point(s) of contact for trade compliance matters, including license-related inquiries, to promote accountability and consistency in approach to interpreting the licenses. Assessing the scope of applicable licenses and exceptions can be technical—ideally, such determinations should be made by appropriately qualified personnel. Second, companies may train employees to confirm that a contemplated transaction is permissible pursuant to a license (or exception codified in the Export Administration Regulations) with a designated trade compliance contact before moving forward with the transaction.

[1] UMI had entered into a settlement agreement with BIS in 2013 related to the same or similar conduct. OFAC agreed to accept payment of only $15,400 if UMI satisfied the terms of the BIS settlement, including (1) satisfactory completion of a two-year probation period, and (2) prompt implementation of an export compliance program.

Finally, companies with extensive international operations may establish a central repository for housing export licenses and authorizations. In addition to expediting access to export authorizations by relevant personnel, creation of a centralized repository may facilitate ongoing monitoring of compliance with license conditions.

C. Failure to Identify Clinical Trial-Related Risks

Clinical trials present a host of complex—yet frequently overlooked—export compliance considerations. Many items used in the conduct of clinical trials may be subject to export control restrictions—for example, electronic devices (*e.g.*, laptops, tablets, and cell phones) with encryption technology used for data collection, biological agents, and laboratory equipment. Further complicating compliance efforts, a single clinical trial may have trial sites in multiple foreign countries, each with its own export and import control regimes and requirements. Finally, the prospect of increased sales—which frequently drives violations of sanctions and export control laws by health care companies—is more attenuated in the clinical trial setting. As a result, clinical trial-related activities may receive less scrutiny from compliance and audit personnel.

Many clinical trial sponsors choose to outsource, to varying degrees, export and import compliance-related tasks to third parties, such as technology suppliers or contract research organizations. Depending on the circumstances, delegation of export compliance activities, such as obtaining licenses, may not relieve the sponsor of responsibility for ensuring compliance with applicable laws. For this reason, an important step in mitigating clinical trial-related export and import compliance risks is the careful selection and vetting of prospective third party services providers. Companies involved with clinical trials also may seek contractual protections and/or indemnification provisions from third parties. In addition, sponsors and vendors alike may consider consulting with vetted, in-country resources in unfamiliar jurisdictions (*e.g.*, local counsel, customs brokers), to ensure compliance with local laws.

D. Historical Liability for Acquisition Targets

Pharmaceutical and medical device companies frequently acquire other health care companies. A company that purchases a health care target with known (or unknown) liability for economic sanctions or export control violations may assume the target's liabilities, depending upon the relevant facts and transaction structure. For example, Ellman International, Inc. ("Ellman"), a U.S.-based manufacturer of devices used in surgical and aesthetic procedures, was purchased by a private equity group in 2008. Unbeknownst to its purchasers, Ellman had violated the Iranian sanctions by (1) indirectly exporting products to Iran through a distributor in Dubai, and (2) engaging the services of an Iranian physician. Upon discovering these potential violations, Ellman's new owners self-reported the Iran transactions to OFAC. In January 2013, Ellman agreed to pay $191,700 to resolve its liability stemming from its pre-acquisition conduct.

Appropriately, many prospective purchasers of health care companies seek to mitigate historical liability risk through pre-acquisition due diligence and negotiation of trade-related representations in purchase agreements. Pre-acquisition due diligence and contractual protections are important—but not necessarily sufficient—risk mitigation steps for transactions involving higher risk targets. In many cases, the representatives of targets who participate in the due diligence process are unfamiliar with the target's trade compliance controls or lack sufficient insight into the target's supply chain to respond effectively to sanctions- and export-related inquiries. And, as discussed above, violations frequently arise in the context of indirect exports, which are unlikely to be reflected in the sales and financial information provided in response to written diligence requests. Finally, while many prospective targets will represent that they are not aware of any historical violations of sanctions or export control laws, such representations are only as reliable as the strength of the targets' existing compliance controls. For example, historical sanctions violations would be difficult to identify if a target lacks formal restricted party screening procedures.

Where comprehensive, pre-signing sanctions and export control diligence is impracticable—or a prospective target presents an enhanced risk profile—purchasers should consider conducting supplemental diligence after signing, to identify and address any ongoing violations. In addition, where existing controls are insufficient, purchasers should require the newly acquired target to promptly implement appropriate compliance enhancements. Enforcement actions show that U.S. regulators are willing to give meaningful credit to purchasers that remediate the underdeveloped compliance programs of acquired companies. For example, in the Ellman case, OFAC treated the purchaser's' prompt disclosure and remedial efforts as mitigating factors when calculating the applicable penalty.

II. CONCLUSION

U.S. regulators are carefully scrutinizing companies' compliance with sanctions regulations and export control laws, violations of which may result in significant penalties and disproportionate reputational costs. U.S. sanctions and export control laws impose strict liability for civil violations , and regulators commonly allege multiple violations per transaction. Due to their size and geographic footprint, health care companies are potentially attractive enforcement targets for regulators.

Because investigations of violations of sanctions and export control laws tend to span multiple years, it is likely too early to assess whether we are at the early stages of an industry sweep (similar to previous FCPA-focused sweeps of the health care industry). As an upfront investment in compliance could stave off a future, high-profile settlement, health care companies may benefit from assessing their existing controls and addressing any potential deficiencies.